


DECLARATION OF CONFORMITY



Product name / Trade name	IDS-iSYS Multi-Discipline Automated System	REF IS-310400
Product name / Trade name	ZENIT RA	REF 42675
Product name / Trade name	TGS TA	REF TGS00001
BASIC UDI-DI: 3760173851003YL	GMDN: 56725	EMDN: W0201020102
 <p>Immunodiagnostic Systems France 42 Rue Stéphane MAZEAU 21320 Pouilly en Auxois France</p> <p>SINGLE REGISTRATION NUMBER: FR-MF-000023843</p>		

RISK CLASS: A B C D

CLASSIFICATION RULE (ANNEX VIII) : Rule 5b

CONFORMITY ROUTE: ANNEX IX Full Quality System (Class B, C & D)

ANNEX I & II+III
(non-sterile Class A)


CE Marking Date: 25 May 2022

COMMON SPECIFICATIONS: Not Applicable

We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above-mentioned product(s) meet(s) the provisions of the following Regulation(s)/Directives

- Regulation EU 2017/746 on *In vitro* Diagnostic Medical Devices
- Directive 2014/30/EU on the relating to electromagnetic compatibility
- Directive 2014/35/EU relating to the making available on the market of electrical equipment designed for use within certain voltage limits
- Directive 2011/65/EU on the restriction of use of certain hazardous substances in electrical and electronic equipment
- Directive 2012/19/EU on waste electrical and electronic equipment (WEEE)
- Regulation (EC) No 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH)

Date: 25 May 2022 Signed on behalf of Immunodiagnostic Systems France SAS

Place: Pouilly En Auxois

 Anne SEIGNEZ
 Quality & RA Manager

Date: 25 May 2022 Signed on behalf of Immunodiagnostic Systems Limited

Place: UK

 Mick HENDERSON
 RA Manager